CHAPTER 4. QUALITY CONTROL INFORMATION

This Chapter provides sequentially, those procedures to be used by all Activities that store medical materiel.

4-1. QUALITY CONTROL

Medical logistics activities (IMSA/MSA/MEDLOG Bn/USAMMCE/Army Pre-Positioned Stock (APS)) are the focal point for all Quality Control Information, which includes-

a. Dissemination and collection Medical Material Quality Control (MMQC) information.
b. Establish and operate medical materiel surveillance programs. To include registering and maintaining materiel in the DoD/FDA SLEP Program.
c. Act on all Quality Control (QC) information by ensuring that all sequentially numbered USAMMA Quad-Service DoD-MMQC; vendor generated messages; SB 8-75 series and recall notices from the supporting commercial distributors' PV are received, registered, validated, observed and disseminated to all customers.
d. Act on all sequentially numbered DoD/FDA SLEP Messages.
e. Provide QC information to medical receiving, storage, shipping, and maintenance elements and to supported activities that consume medical materiel.
f. Provides QC information (such as reports of materiel defects) to the wholesale system based on surveillance findings and reports from customers.
g. Prepares reports or takes other actions as required by regulation, *SB-8-75-S7*, *SB-8-75-S10* (ARNG only) and this SB.
h. Ensures that materiel is stored in such a manner as to prevent deterioration and in accordance with manufacturer's guidance.
i. Act as a source of QC information by conducting a constant surveillance program of medical materiel in storage or use.
j. Dispose of unserviceable materiel through the use of national, regional, or local disposal contracts.
k. Provides logistics assistance to supported units for QC matter.

4-2. SOURCES OF QUALITY CONTROL INFORMATION

a. The Quality Control Information is disseminated in the following ways:

(1) Department of Defense MMQC (DoD-MMQC) messages
(2) Army Medical Materiel Information (MMI) messages
(3) DoD/FDA Shelf Life Extension Program Messages (SLEP)

b. Procedures**:** Supply accounts at the IMSA/MSA/MEDLOG Bn/USAMMCE/APS level will maintain a record, either automated or manual, of these messages in numerical sequence. As a minimum, the data will reflect the date received, message number, NSN (or other identifying number), nomenclature, action required, and remarks. If a message is missing, initiate tracer action through message-routing channels or obtain a copy from either:

(1) World Wide Web Address: **http://www.usamma.army.mil**

(2) Commander, USAMMA
ATTN: MRMC-MMO-SO
1423 Sultan Dr., Suite 100 Fort
Detrick MD 21702-5001

(3) The DoD/FDA SLEP System:
https://slep.dmsbfda.army.mil

(4) Activities with an automated QC module in their inventory management system, i.e., TAMMIS/DMLSS, are not required to maintain a manual register, except for the DoD/FDA SLEP messages. The MMQC messages and the DoD/FDA SLEP messages will be retained on file for at least the current calendar year and the prior calendar year per *AR 25-400-2.*

c. Transmission:

(1) The DoD-MMQC messages are published on the USAMMA website **(http://www.usamma.army.mil).** Units and activities of the Active Army, USAR, and ARNG, as well as the other services are required to register on the USAMMA website to receive Department of Defense Medical Materiel Quality Control (DoD-MMQC) messages via email. These messages are also disseminated via FTP to USAMMCE (Germany) and 16th MEDLOG (Korea). They are also provided to the JMAR and Defense Medical Logistics Supply System (DMLSS) for dissemination.

(2) The USAMMA MMI messages are also published on the USAMMA website **(http://www.usamma.army.mil).** Only registered US Army Activities, (Active Army, USAR, and ARNG) will receive the MMI messages via email as well.

d. The DoD SLEP Messages are the responsibility of the DMSB. Their website is:
https://slep.dmsbfda.army.mil

(1) Effective 13 June 2005 the DMSB established the DoD/FDA SLEP Web Based System. This system creates is a one-stop shopping for SLEP management and allows each activity to:

Enter their own inventory
View results of FDA testing
View SLEP messages
Be tasked to provide Samples to the FDA for testing
Management of Labels for extensions

(2) Access is limited by password and user permissions. This includes access to the SLEP messages. All testing and extension data provided to the SLEP by the Food and Drug Administration is considered For Official Use Only and cannot be shared with anyone outside the user's organization. Sharing this information with local, civilian counterparts is a violation of the terms agreed to by the FDA but also a violation of the Memorandum of Agreement each participant organization signs prior to entering the SLEP program. Non-SLEP organizations that use SLEP information are in violation of Federal law (Code of Federal Regulation 21) that governs "misbranded" pharmaceuticals.

(3) Activities may register for access to the SLEP system. To access the SLEP web application:

- Open your Internet Explorer
- Click on File
- Click on Open
- Type in the following URL https://slep.dmsbfda.army.mil
- Click Okay
- Save this page as one of your favorites

- You should now be at the SLEP Main Page

- Click on USER REGISTRATION on the top Left on the page

  - Read the General Counsel Directive
  - Click Continue

- Scroll down the page and make sure that you have a SUBMIT APPLICATION button at the bottom of the page. If you do not see it, close your Internet Browser and begin again, your browser did not completely load

- If SUBMIT APPLICATION button is at the bottom of the form, complete the form, please make sure you tell why you need access to the SLEP System, but you are limited to 4 lines. Make sure you use your Activity's FedEx Address (Street, Building and Room Number). This address is where your labels will be sent.

- Once you have access to the system, go to INVENTORY, down load and print the INVENTORY HELP. This is part of the Users Manual, and will be you help until version 2, is completed fall 2006.

Your Password and User ID will be sent to you in 1-2 working days after your Security Officer has responded back to the email requesting verification that you have a positive National Agency Check (NAC).

See the SLEP FAQ on the LEFT side of the MAIN Menu before email questions to:
DMSBDOD-FDASLEP@AMEDD.ARMY.MIL

(4) Activities must be registered to receive SLEP messages. Only SLEP Messages for FY04 and before are available on the USAMMA Web site. All SLEP Messages from 2005 forward are on the DoD/FDA SLEP Web Site.

e. The IMSA/MSA/MEDLOG Bn/USAMMCE/APS are responsible for making distribution of messages to support customers, minus the DoD/FDA SLEP Messages; they are for internal use only.

f. Army National Guard actions: Upon receipt, Chief, National Guard Bureau (NGB) will distribute copies of all MMQC messages to DMSO and ARNG training sites operating troop medical clinics. Additionally, the Chief, NGB, will immediately distribute all MMQC messages concerning Type I medical materiel complaints and the FDA Class I recalls to the State Safety Office and all medical elements in the State, including separate medical detachments and medical sections of maneuver battalions. ARNG units who store stockpiles of medical materiel, e.g. the Weapons of Mass Destruction Civil Support Teams (WMD-CST) will register and maintain their inventory in the DoD/FDA SLEP System as directed by the National Guard Bureau and SB-8-75-S10.

g. The USAR action: The MEDLOG Bns and USARC medical units designated as a SSA within a command or area of operations are responsible for the distribution of all applicable DoD-MMQC messages to supported customers, minus the DoD/FDA SLEP Messages; they are for internal use only. USAR medical units, e.g. MEDLOG Bns, ASMB and hospitals will register for the DoD/FDA SLEP program upon mobilization.

h. On-line query search: The USAMMA has an on-line query capability for all QC messages, SLEP messages before FY05, and information bulletins. Search by Message MMQC/MMI Number, NSN, National Drug Code (NDC), Subject, or Lot Number by accessing the USAMMA homepage at http://www.usamma.army.mil

i. The *SB 8-75 series:* The SBs are distributed through normal Army distribution channels and provide other essential medical logistical information.

j. The *AR 702-18, DLAR 4155.37,* and *AFR 67-43:* These publications contain storage QC procedures and serviceability standards applicable at all levels of materiel management. Questions related to information contained in the publications may be directed to:

Commander, USAMMA
ATTN: MCMR-MMO-PM
1423 Sultan Dr., Suite 100
Fort Detrick MD 21702-5001

The MEDSILS, FLIS, AMDF, FEDLOG, and, UDR: The MEDSILS, AMDF, or FEDLOG, UDR, and FLIS are the official sources of supply management data, i.e., Shelf Life Codes (SLCs), and AAC. They have precedence over conflicting data published in other Army publications as well as *AR 702-18, DLAR 4155.37,* and *AFR 67-43,* unless otherwise stated in DoD-MMQC messages. Issues with Shelf Life codes may be sent to DSCP through https://dmmonline.dscp.dla.mil, NSN Action Feedback Form or to the DoD/FDA SLEP Program, DMSBDOD-FDASLEP@AMEDD.ARMY.MIL

4-3. STORAGE PROCEDURES AND SHELF LIFE OF MEDICAL MATERIEL

a. All activities that store medical materiel are responsible for the--
(1) Care, preservation, and surveillance of all medical materiel under their control.
(2) Establishment of storage policies for the materiel they store.

b. Store medical materiel in unit of issue and/or unit of measure. Establish stock control records for both unit of issue and unit of measure items. Determine the unit of measure price by dividing the unit price by the number of units of measure in the unit of issue.

$$\frac{\text{Unit Price}}{\text{\# of Units of Measure in the Unit of Issue}} = \text{Unit of Measure Price}$$

c. Storage conditions. Specialized procedures and equipment are required to prevent the deterioration of medical materiel in storage. Medical materiel is frequently sensitive to sunlight, heat, and moisture. Therefore,--

(1) Emergency or battery-powered temperature alarm systems will be used on refrigerator storage units at the IMSA/MSA/MEDLOG Bn/USAMMCE/APS. Alarms will be electrically monitored on a 24-hour basis. This can be done manually or through technical design. Items requiring refrigeration will be stored and shipped at temperatures between 35

and 46º Fahrenheit (2º and 8º Celsius (C)) and frozen items at temperatures below 32º Fahrenheit (0º C).

(2) Heat, refrigeration and humidity control will be provided when necessary to protect medical materiel in accordance with all special instructions on the item, shipping label, manufacturer/product's literature, *UDR*, *TM 743-200-1* or in the FSC. IMSA/MSA/MEDLOG Bn/USAMMCE/APS sites that are storing stockpile of materiel will maintain an automated or manual log of the daily temperature and humidity in the storage facility. This information will be reported in the DoD/FDA SLEP System on a monthly basis. Normal temperature for pharmaceutics as defined by the US Pharmacopeia as Controlled Room Temperature is 68-77 degrees Fahrenheit at 60 relative humidity and allows for a variation of between 59-86 degrees Fahrenheit which may be experienced in pharmacies, hospitals and warehouse.

(3) X-ray film will be stored per manufacturer's recommended storage methods, usually on edge in a vertical position. Film may fog if stored horizontally.

(4) Dry-cell batteries will be removed from instruments prior to storage.

(5) Rubber goods will be stored in rolls or laid flat. Talc will be used to separate surfaces.

(6) Controlled items that require special storage and handling procedures to protect against theft, will be stored per *AR 190-51, AR 40-2* and chapter 3 of this *SB*.

(7) Hazardous materiel, including acids, flammables, corrosives, gasses, and poisons will be stored per:

(a) *TM 743-200-1*.

(b) *TM 38-410/DLAM 4145.11/Navy Supply Publication (NAVSUP PUB) 573/AFR 69-9/MCO 4450.12*.

(c) *AR 200-1*.

(d) Applicable Federal, state and local laws

(8) When placing medical materiel in storage, at a minimum, consider the following;

(a) Temperature

(b) Compatibility of chemicals.

(c) Ventilation.

(d) Fire protection.

(e) Spill prevention and response.

(f) Containment.

(g) Protection from the weather.

(9) Post an inventory list and all applicable MSDSs near the storage area within the activity.

(10) Suspended materiel will be physically separated from other stock and marked with the authority for suspension, e.g. DoD/FDA SLEP Message Number xx, MMQC Message yy

d. Storage QC records. The IMSA/MSA/MEDLOG Bns/USAMMCE will maintain supplemental records for all expiration-dated materiel that is stockpiled. This record will be maintained in the DoD/FDA SLEP System. Other medical supply operations will maintain QC records in accordance with command or command surgeon guidance. As a minimum, QC records will reflect the manufacturer, lot number, and current expiration date. The DA Form 4996-R (Quality Control Card) will only be used for activities without automated records, i.e., TAMMIS/DMLSS QC module, will be used and for non-stockpiled medical materiel. The DA Form 4996-R can be reproduced locally on 8-by 5-inch card stock. A copy for reproduction is located in the back of this regulation. Table 4-1 provides the preparation steps for DA Form 4996-R. Use QC records to--

(1) Ensure rotation of stocks.

(2) Prepare reports of items that cannot be used prior to expiration for extension, disposal, or destruction.

(3) Budget for replacement of expired stocks.

e. Marking potency extensions. Medical items in storage whose potency expiration date is being extended will be re-marked with the new expiration date. The DoD/FDA SLEP will send you labels for each item extended in the SLEP program. The label must be placed on each item, covering the current expiration date, before it may be issued. The large labels are to be used on the carton/box/pallet. The smaller labels are to be used for the individual item. The quantities and lots of labels that are sent are based on the current on-hand inventory your activity has in the SLEP system. You may not line out expiration dates. Additional direction on placement and use of the labels will be on the back of each label or as directed by USAMMA.

Table 4-1. Steps to Preparing DA Form 4996-R

Step	Description
1	NSN: NSN/MCN/universal product number/NDC (pen entry)
2	Description: Name of item (pen entry)
3	Inspection frequency: How often does this item need to be inspected? (See *AR 702-18/DLAR 4155.37/AFR 67-43, UDR,* or *Defense Logistics Information System (DLIS)*
4	Date last inspected: (pencil entry)
5	Date next inspection: (pencil entry)
6	Manufacturer: Name of manufacturer. There may be more than one.
7	Lot number: Lot number from package.
8	Expiration date: Expiration date on package, if applicable.
9	Date manufactured: Date manufactured on package, if applicable.
10	Shelf life: Type I (excluding pharmaceuticals/drugs), Type II, and Estimated Storage Life (ESL) from FEDLOG or UDR
11	Date received: (pencil entry)

4-4. DETERMINING SHELF LIFE FOR MEDICAL MATERIEL

a. The Shelf Life of an item begins when it is manufactured. The 21 CFR requires all Pharmaceutical items to have an expiration date (potency and dated) (P&D) on them. The US Pharmacopeia (USP) founded in 1820, is a nongovernmental, nonprofit organization whose mission is to promote public health and is recognized by Federal law as the official body that sets standards for prescription drugs. The USP defines the expiration date as "the time during which the article may be expected to meet the requirements of the pharmacopeia monograph provided it is kept under the prescribed conditions." The expiration date, which limits the time during which the article may be dispensed or used, is based on scientifically sound stability studies carried out by the manufacturer and is usually expressed in terms of the month and year, as stated on the manufacturer's container. This means that the product may be used until the last day of the stated month and year, unless it has been extended by the FDA through empirical testing at its labs through the DoD/FDA SLEP program. Medical materiel storage periods are categorized as follows:

(1) Type I shelf life items. Type I items are those items of supply having a definite storage period terminated by an expiration date that was established by empirical and technical test data. Routinely, these supply items are considered non-extendable except when large quantities are being stored for contingency purposes. In these cases, the supply item may qualify (based on technical and economic considerations) as a candidate for the DoD/FDA SLEP. This program requires testing by the FDA. Type I shelf life items are identified by "01" in the fourth and fifth positions of the MCSC and by an alpha character in the SLC.

(2) Type II shelf life items. Type II items are those items of supply having a definite storage period terminated by an expiration date that may be extended after a prescribed inspection or restorative action. They are identified by "02" in the fourth and fifth positions of the MCSC and by a numeric entry in the SLC.

(3) Shelf life condition codes. Shelf life medical materiel is condition coded per *AR 702-18/DLAR 4155.37/AFR 67-43* as follows:

(a) Condition code A - 6 months remain on the shelf life.
(b) Condition code B - 3 to 6 months remain on the shelf life.
(c) Condition code C - less than 3 months remain on the shelf life.

(4) Reclassified materiel. Medical materiel bearing expiration dates are reclassified from condition code A to B or C based upon the number of months remaining in the unexpired dating period. This is automatically done to the items in the DoD/FDA SLEP system. The CONUS and OCONUS activities may receive condition code A stocks for shelf life materiel issued from DSCP. Condition code B stocks are issued only to CONUS activities unless the OCONUS activities, with prior approval, have agreed to accept Condition Code B stocks. Activities will report, using the shipping discrepancy report, chapter 3 of this SB to report any potency dated materiel, which OCONUS activities receive with a shelf life condition coded B or C or CONUS activities receive with a shelf life condition coded C.

b. The FDA, under the DoD/FDA SLEP is the approving authority for medical extensions on Type I shelf life items.

c. The Shelf Life of a medical item is only for the period of time it is in storage. Once it is removed from storage, its Service life begins. The Service life for a medical item is the period of time it may be used after it is removed from storage and or issued. It is determined by:

(1) How was it stored?
(2) Its current expiration date
(3) The number of hours, days, months it may be used after it is mixed or removed from refrigeration or the freezer, e.g. Pyridostigmine Bromide Tables may only be out of the refrigerator for a total of 90 days to be eligible to be issued to an individual.
(4) A maximum of one (1) year from the day issued, per the US Pharmacopeia <1136>

4-5. MANAGEMENT OF SHELF LIFE ITEMS

a. Medical logistics activities to include Army Pre-positioned Stocks, MCDM, Unit Deployment Packages (UDP), Installation CBRN, and any other stockpile of Army medical materiel:

(1) Register and participate in the DoD/FDA SLEP Program.
(2) Issue the earliest dated materiel first.
(3) Enter on-hand, stockpiled inventory in the SLEP system as soon as the items are received and update the inventory on a quarterly basis.

(4) Store all materiel in a controlled environment under conditions recommended by the manufacturer. Those stocks that were stocked outside of the manufacturer's recommended storage parameters will be reported to USAMMA, ATTN: MCMR-MMO-PM.

(5) Maintain an automated or manual log of the daily temperature and humidity in the storage facility. This information will be reported in the DoD/FDA SLEP System on a monthly basis. Normal temperature for pharmaceutics as defined by the US Pharmacopeia as Controlled Room Temperature is 68-77 degrees Fahrenheit at 60 relative humidity and allows for a variation of between 59-86 degrees Fahrenheit which may be experienced in pharmacies, hospitals and warehouse

(6) Send all samples requested by the FDA for testing with-in 14 days of the request. Instructions on how to ship and where to ship to is on the DoD/FDA SLEP site, SLEP message 2005-57.

(7) Comply with all directions that are in the DoD/FDA SLEP message, e.g. suspend, destroy, re-label.

(8) Re-Label all products in accordance with the SLEP message. As a minimum, you must re-label the exterior package/pallet/box. The individual items do not need to be labeled until you go to issue it.

(9) See SB-8-75-S7 for additional directions on management of MCDM, APS, UDP and the DoD/FDA SLEP Program.

b. Biologicals. The FDA will not accept shelf life extension requests for FSC 6505 items classified as "biologicals", e.g. vaccines or lab reagents. The USAMMA will provide guidance through MMQC messages on reporting and disposal of biologicals.

4-6. SURVEILLANCE OF MATERIEL

a. All activities that stock medical materiel will establish a surveillance program to provide for the scheduled inspection of medical materiel. When appropriate, activities should rotate mobilization reserve stocks with operating stocks. Timely action is necessary to preclude undue loss through deterioration or destruction.

The basic publications and systems used for surveillance programs are:

(1) MEDSILS, FLIS, AMDF, FEDLOG and UDR
(2) *AR 702-18/DLAR 4155.37/AFR 60-10*, Appendix M
(3) *DA SB 8-75* series
(4) Military Item Disposition Instructions (MIDI)
(5) Universal Data Repository (UDR)
(6) Defense Logistics Information System (DLIS)
(7) Military Environmental Information Source (MEIS)
(8) DoD-MMQC messages
(9) DoD/FDA SLEP messages

b. *AR 702-18/DLAR 4155.37/AFR 60-10, and DLAM 4155.5*, Appendix M, contains the procedures and standards for visual inspections of medical materiel. The standards identify the physical properties (discoloration, precipitation, odor change, and so forth) that would indicate product deterioration and render the item unsuitable for issue and use. The Appendix M is available for viewing on the USAMMA web site at http://www.usamma.army.mil/

4-7. INSPECTION OF LOCALLY PURCHASED MATERIEL

a. Personnel assigned to the receiving section of the IMSA/MSA/MEDLOG Bn/USAMMCE/APS will inspect all materiel before acceptance. When materiel is delivered direct to the activity/requester, individuals receiving materiel are required to conduct an inspection prior to acceptance. The SLEP messages should be used for this surveillance. Furthermore, IMSA/MSA/MEDLOG Bn/USAMMCE/APS should report any problems discovered relative to usage as medical materiel complaints. This requires a visual inspection of materiel to ensure that the product appears in good condition. For specialized materiel requiring inspection expertise beyond the capabilities of the IMSA/MSA/MEDLOG Bn/USAMMCE/APS, the requester or other appropriate specialist should assist in the inspection. The supporting medical maintenance activity will perform technical inspections of all medical equipment as appropriate. Receiving reports will be processed in a timely manner. Report problems with materiel identified after the receiving report has been processed to the supporting contracting officer for appropriate resolution. The USAMMA can provide assistance in specialized or technical inspections.

b. The IMSA/MSA/MEDLOG Bn/USAMMCE/APS or credit card holder will respond within the scope of their authority using local credit card procedures to resolve the issues. Contact the issuing contracting office for further resolution as required.

c. The receiving activity/requester must forward a copy of the MSDS when direct delivery occurs to the IMSA/MSA/MEDLOG Bn/USAMMCE/APS and comply with the activity's hazard communication program.

4-8. RECALL OF NONSTANDARD DRUGS AND DEVICES

a. A nonstandard drug is any item that does not have a DMSB-approved NSN. Nonstandard drugs and devices announced by the FDA as being recalled by manufacturers or distributors will be published in DoD-MMQC messages.

b. Activities having quantities of these items on-hand will suspend the materiel from issue and use.

c. The CONUS activities will contact the respective manufacturer or distributor for disposition instructions.

d. The OCONUS activities will comply with DoD-MMQC messages. If further disposition instructions are required, report NSN and quantities suspended to:

Commander, USAMMA ATTN: MCMR-MMO-SO
1423 Sultan Dr., Suite 100
Fort Detrick, MD 21702-5001

except as indicated in para 4-6.f. Reports must include the following items:

MMQC message reference
Nomenclature
Lot or batch number
Quantity
Requisition number under which the materiel was obtained
Purchase order or contract number
Location of the materiel.

e. The USAMMA will coordinate with DSCP or the manufacturer for disposition instructions and will advise the reporting activities.

f. The OCONUS activities may contact the responsible manufacturer or distributor for items procured directly from an overseas acquisition source other than DSCP.

4-9. DISPOSAL AND DESTRUCTION

The preferred method of destruction is using contracted services for disposal of unserviceable medical materiel. In the event that the item(s) cannot be disposed of using contracted services, then local destruction of unserviceable medical materiel is authorized. Local destruction is restricted to those items approved by the Environmental Science Officer (ESO) of the Preventive Medicine (PMed) Service consultants or ESO from the RMC/MSC.

a. The IMSA/MSA/MEDLOG Bn/USAMMCE/APS will accept items for destruction from any activity that is not capable of accomplishing destruction actions. This acceptance constitutes informal accountability and storage by the IMSA/MSA/ MEDLOG Bn/USAMMCE pending review by the ESO destruction officer. The IMSA/MSA/MEDLOG Bn/USAMMCE/APS will sign the DA Form 3161 (Request for Issue or Turn-In) from the activity to show acceptance and storage of the items pending environmental review and destruction.

b. Medical materiel accepted by the IMSA/MSA/MEDLOG Bn/USAMMCE/APS will be recorded on a DA Form 3161, prepared by the activity desiring destruction per this regulation and clearly marked “FOR DESTRUCTION PURPOSE ONLY” (see Table 4-1). Document numbers for the DA Form 3161 will be assigned by the activity preparing the document. The IMSA/MSA/MEDLOG Bn/USAMMCE/APS will also assign a voucher number to the document (considered a debit/credit voucher and not posted to the accountable records) for internal control and filing.

c. Medical materiel authorized for destruction will be processed as follows:

(1) The fixed facility HCA or deployable unit commander will appoint a disinterested officer (E7/GS 07 or above) to be responsible for all destruction at the IMSA/MSA/MEDLOG Bn/USAMMCE/APS or deployable unit and for controlled substances at the user level.

(2) The ESO/destruction officer will certify as to the accuracy of all facts entered on destruction documents. Units not authorized TAMMIS-Medical Supply (TAMMIS-MEDSUP/DMLSS) may use DA Form 3161 as their destruction document (see table 4-1). Activities using TAMMIS-MEDSUP/DMLSS will use the system generated destruction document. The statement shown in Figure 4-1, signed by two witnesses, will be placed on the destruction document below the signed certificate of the ESO/destruction officer.

d. The Military Item Disposal Instructions/Military Environmental Information Source provides guidance for the destruction of materiel. If a method of destruction code is required but not assigned, contact:

Commander, U.S. Army Center for
Health Promotion and Preventive Medicine
ATTN: MCHB-TS-EHM
5158 Blackhawk Rd.
Aberdeen Proving Ground MD 21010-5403

Items included are as follows:

(1) Unidentifiable items or items which, when intended to be disposed of, are hazardous wastes according to criteria developed under the authority of Public Law 94-580 and its implementing Federal and state regulations, such as Parts 260-270, Title 40 *(40 CFR 260-270).*

(2) Partially used items that are excess. These items tend to deteriorate faster after the opening of a container. The packing list or attached covering label may not actually describe the contents of the container.

(3) Items cited for destruction by the MMQC or MMI messages

(4) Items cited for destruction by the DoD/FDA SLEP messages and the SB 8-75 series.

(a) When a contractor disposes of hazardous waste, contracts will contain a statement requiring the contractor to furnish a certificate of destruction with the invoices for payment. Follow-up will be made on the status of destruction when invoices are received without a certificate of destruction.

(b) A witnessing statement on the DA Form 3161 is not required when a contractor accomplishes destruction of hazardous waste.

(c) Local controls will be established to ensure that the contractor is given an itemized listing indicating the product identification number, nomenclature, unit of issue, quantity, and shipping weight of all items to be picked up for destruction. This listing will be filed with the required DA Form 3161.

(5) The completed DA Form 3161 will be used as a voucher for dropping the materiel from accountability. It will cite the reason for destruction, method of destruction (disposal code) (MIDI), and the location of destruction.

(6) When instructed by the USAMMA or DSCP, the medical activity will submit certificates of destruction. Where credits are involved, the local finance and accounting division must also submit MILSTRIP DIC FAE (request for billing adjustment) transaction. This transaction generates interfund credits from the DSCP while the certificate is used by the DSCP to support claims for reimbursement against contractors. (See *AR 725-50*.)

(7) The Chief of Preventive Medicine Service (or designated representative(s)) will review destruction documents from HCA customers and certify that the destruction codes assigned to the items are correct. The installation environmental coordinator will review destruction documents from deployable units that have the capability of performing their own destruction actions. The destruction codes will be checked using the publications stated above. The following statement will be cited on all destruction documents and will be signed by the ESO or installation environmental coordinator:

"I certify that the destruction codes assigned to the above items are acceptable, environmentally sound, destruction/disposal methods for this materiel, and comply with Federal, state, and local laws."

(8) Materiel in less-than-unit-of-issue quantity will be informally accounted for pending destruction. Keep a copy of the turn-in document with the materiel until destruction. Upon destruction, file the copy with the destruction certificate.

(9) Note R and Q drugs less-than-unit-of-issue quantities will not be turned in to IMSA/MSA/MEDLOG Bn/USAMMCE/APS. They will be returned to the supporting pharmacy for destruction.

Table 4-2. Steps to Preparing DA Form 3161 as a Destruction Document

Step	Description
1	**Sheet Number:** Self-explanatory.
2	**Number of Sheets:** Self-explanatory.
3	**Voucher Number:** Self-explanatory.
4	**Send to:** Destruction.
5	**Request from:** Activity/unit desiring destruction.
6	**Item Number:** Self-explanatory.
7	**Stock Number:** Enter NSN, MIIN (Medical Item Identification Number), NDC, UPN, or MCN.
8	**Item Description:** Brief nomenclature, manufacturer, lot number, expiration date/manufacture date, and reason for destruction, e.g., expired, MMQC message, manufacturer's recall, broken, non-returnable excess.
9	**Unit of Issue:** Self-explanatory.
10	**Quantity:** Enter quantity to be destroyed.
11	**Code:** Destruction Code from the MIDI, U.S. Army Center for Health Promotion and Preventive Medicine, or activity ES/PMed officer. If the code is obtained from other than the MIDI, state from whom and when.
12	**Supply Action:** The quantity actually destroyed. Entered by Destruction Officer.
13	**Unit Price:** Self-explanatory.
14	**Total Cost:** Self-explanatory.
15	**Sheet Total:** The sum of all lines on the sheet.
16	**Grand Total:** The sum of all sheet totals for the same voucher number.
17	The document will be closed with either "LAST ITEM" or "NOTHING FOLLOWS."
18	The certificate of the destruction officer will begin on the next available line or on a continuation sheet. The certificate will be signed and dated. The typed name and grade of the destruction officer will be entered. The certification statement should state specifically how each line was destroyed following the codes assigned and definitions provided in the SB 8-75 series. **NOTE:** If the items are turned over to a contractor for destruction, the name of the contractor will be shown, the destruction certificate will be changed to reflect this action, and the representative will sign for receiving the items in the presence of the two witnesses.
19	If the materiel is buried in an on-post landfill, the grid coordinates of the site will be shown. If using an off-post landfill, include specific address (street, city, state) and grid coordinates. If the materiel is incinerated, include the on-post building number or specific off-post address
20	The witnesses' statement (see the sample in figure 4 below), will start on the next available line. The statement will be signed and dated by both witnesses. Be sure typed names and grades are shown.
21	The certification of the ESO/destruction officer will begin on the next available line. When an ESO is not assigned, the appointed Destruction Officer will sign the certification. This certification is required for Federal, state, and local environmental standards.
22	Add a statement on the destruction document that credit was sought but not granted if the destruction includes nonstandard drugs or biologicals with a line acquisition value of $100 or more and replacement or credit was not obtained

Figure 4-1, below, is an **example** of how the Destruction Statement Format should be written.

I have witnessed the destruction of the materiel described and it was destroyed on the date and in the manner stated. (Signature) Witness 1) (Typed name, Witness 1)) (Signature) Witness 2) (Typed name, Witness 2))

Figure 4-1. Destruction Statement Format

4-10. QUALITY ASSURANCE FOR MEDICAL GASES

a. Bulk (liquid) gases may be oxygen or ethylene oxide. The Quality Assurance (QA) procedures for bulk (liquid) gases are:

(1) The HCA Commander will designate in writing, those individuals who must have received training in the use of the gas analyzer as being responsible for monitoring bulk gas deliveries. These individuals will:

(a) Document name of individual responsible for receipt of bulk gas and date and time of delivery.

(b) Document the results of gas analysis before acceptance.

(c) Document amount received.

(d) Document corrective actions if gas fails to meet standards (less than 95 percent by volume for oxygen).

(e) Maintain accuracy of gas analyzing equipment.

(2) The HCA Commander will ensure that the bulk gas storage container has an outlet that allows for gas analysis. Specific storage procedures for bulk gases are found in *AR 700-68* and NFPA codes.

(3) Records of receipt and gas analysis must be maintained for two years per *AR 25-400-2.*

(4) The HCA Commander will establish a written plan to handle bulk gas emergencies (medical gas alarms or equipment failures). This plan must identify clinical areas requiring alternate gas supply until the central supply is functioning properly.

(5) Equipment using bulk gases must be tested for proper functioning before patient's use. Follow manufacturer guidelines to complete this testing.

(6) The HCA Commander must ensure that all personnel handling bulk gases are properly trained. Training must be documented.

b. Medical gases maintained in cylinders require QA procedures.

(1) Upon receipt, the cylinders containing oxygen must have DD Form 1191 (Warning Tag for Medical Oxygen Equipment) attached (*TB MED 245*).

(2) Cylinders containing any gas must have the cylinder valve cap in place when so designed.

(3) Cylinders must be inspected upon receipt for proper color-coding, bulges, or damage (*MIL-STD-101*).

(4) Cylinders must be stored per NFPA codes and *AR 700-68*.

(5) Cylinders cannot be refilled and shipped if past retest date(s). It is permitted to continue to use gas from a cylinder that is past due for retest. No time limit is imposed.

(6) Safe handling practices of cylinders *(TB MED 245)* must be followed.

(7) Disposal and turn-in procedures are contained in *AR 700-68,* Sections 7 and 8.

4-11. SUBMITTING MEDICAL MATERIEL COMPLAINTS

a. All medical materiel complaints, regardless of procurement source, will be submitted on a Complaint Form to DSCP via online at https://dmmonline.dscp.dla.mil/forms/mpqdr_entry_new.asp

b. Complaint Forms completed on nonstandard items procured through DSCP must cite the purchase order number and document number.

c. Report the circumstances of Type I complaints immediately to DSCP, through the quickest means, that is, by telephone or immediate message.

(1) During normal duty hours (0700 - 1700 hours Eastern Time), call the DSCP ESOC at DSN 444-2111/2112, or commercial 215 737-2112. A fax may also be sent to: Commercial 215 737-2081/7109 or DSN 444-2081/7109.

(2) After duty hours, the numbers called above will automatically transfer to the Staff Duty Officer. If the transfer does not occur or the call is not answered, call the following numbers: DSN 444-2341 or commercial 215 737-2341.

d. The HCA submitting Type I complaints will document the call immediately and send written confirmation within 12 hours via facsimile or submit a Complaint Form online. For Type I complaints only, the identity and contact information for the authorizing Medical Officer is required. When a Type II or III complaint is determined appropriate, the medical unit will submit the Complaint Form within 48 hours either by mail to the DSCP address shown below, facsimile to DSN 444-3120/Commerical 215-737-3120, telephonically to DSN 444-2891/Commerical 215-737-2891 or online**.**

Director, DSCP
ATTN: DSCP-MRCM
700 Robbins Ave
Philadelphia PA 19111-5092

e. Follow-up by mail or electronically with photographs and drawings of equipment with Type III complaints to help describe or substantiate the complaint.

f. Include a specific statement on the storage conditions of the materiel on the Type II complain. An example of the statement would be: “Controlled temperature warehouse or unheated warehouse.”

g. Forward copies of the Complaint Form as directed below:

(1) If not submitted online**,** forward one copy of complaints regardless of procurement source to:

Director, DSCP
ATTN: DSCP-MRCM
700 Robbins Avenue
Philadelphia PA 19111-5092

(2) One copy of complaints on standard and nonstandard materiel purchased locally to the appropriate local contracting activity.

(3) One copy of complaints for GSA catalog materiel to the GSA regional office.

(4) Information copies of all complaints will be sent to the following addressees

(a) Defense Medical Standardization Board
ATTN: Staff Director
1423 Sultan Drive
Fort Detrick MD 21702-5013

(b) Commander, USAMMA
ATTN: MCMR-MMO-SO
1423 Sultan Drive, Suite 100
Fort Detrick MD 21702-5001

h. The preferred method for the submission of a complaint is electronic filing of a Complaint Form. This method provides simultaneous copies going to DSCP, the DMSB, and the USAMMA, through the INTERNET at https://dmmonline.dscp.dla.mil/forms/mpqdr_entry_new.asp . Upon submission of the complaint, DSCP acknowledges receipt of the complaint via email or other method.

i. Medical materiel complaints submitted on a Complaint Form are exempted from information requirements control under *AR 335-15*.

j. The 21 CFR prescribes reporting certain materiel/equipment conditions to the FDA under the Safe Medical Devices Act (SMDA). Logistics personnel will coordinate and provide a copy of the Complaint Form to the Risk Manager as part of the Risk Management Program. The Risk Manager is required under Joint Commission on Accreditation of Healthcare Organization (JCAHO) to review the SMDA information on the Complaint Form and assess the potential risk.

Additional reports may be required under *AR 385-40*